APEX BIOTECHNOLOGY CORP
No. 7, Li-Shin Rd. V, Hsinchu Science Park, Hsinchu, Taiwan, ROC
TEL: 886-3-5641952 FAX: 886-3-5678302

K062799

FEB - 6 2007

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **APEX Biotechnology Corp.**
- Address: No. 7, Li-Shin Rd. V, Hsinchu Science Park, Hsinchu, 30078, Taiwan, ROC
- Registration Number: **9616936**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hint.net

  886-3-5208829 (Tel); 886-3-5209783 (Fax)

  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: September 15, 2006

Device

- **Proprietary Name:** Gluco Track® Blood Glucose Monitoring System
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II,

2.2. Safety and Effectiveness Information

- **Predicate Device:**

  Claim of Substantial Equivalence (SE) is made to GlucoSure® Blood Glucose Monitoring System **(K011233)**
- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, Gluco Track Blood Glucose Monitoring System only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 6 seconds.

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- **Intended Use:**

  The Gluco Track Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary, fingerstick whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for both lay use by people with diabetes and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus.

- **Synopsis of Test Methods and Results**

  Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to GlucoSure Blood Glucose Monitoring System **(K011233).** Both of them have the same working principle and technologies. The differences are meter dimension, weight, power voltage, memory data number, date and time setting, auto recall the 7, 14 and 30 days average and some other user friendly designs on meter. As we can see, the differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. They are substantially equivalent.

Dr. Jen, Ke-Min
510k Contact Person for
APEX BIOTECHNOLOGY CORP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ke-Min Jen
Apex Biotechnology Corp.
No. 58, Fu Chium Street
Hsin Chu City, 30067
Taiwan, R.O.C.

FEB - 6 2007

Re: k062799
Trade/Device Name: Gluco Track Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: January 28, 2007
Received: January 30, 2007

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): **K062799**

Device Name: *Gluco Track Blood Glucose Monitoring System*

Indications for Use:

The Gluco Track Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary, fingerstick whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for both lay use by people with diabetes and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus.

Prescription Use _____ AND/OR Over-The-Counter Use __√__

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062799